

REMARKS/ARGUMENTS

Claims 1-23 remain in this application. Claim 1 has been amended to further clarify the claim, claim 6 has been amended to correct the antecedent basis to claim 2, and claims 20 and 21 have been amended as suggested in the Office Action to correct a spelling error. Support for the amendment to claim 1 can be found on page 3, lines 26-28 of the specification. Accordingly no issues of new matter are believed to be raised by the above amendments to the claims.

REJECTION UNDER 35 USC 102(b)

Claims 1-4, 6-9, 11-13, and 20-21 were rejected under 35 USC 102(b) as being anticipated by European Patent Application 429,842 (Hereinafter "Hai ('842)"). See Pages 2-3 of the Office Action. Applicants respectfully disagree.

According to the Office Action "Hai ('842) discloses a method for transporting a molecule through a mammalian barrier membrane of at least one layer of cells comprising the steps of ablating the membrane with a shear device comprising a sheet containing at least one opening and a shear member, where the sheet is contacted with the membrane such that a portion of the membrane is forced through the opening and ablates the portion of the membrane exposes through the opening . . ." See Page 2 of the Office Action. Applicants, however, cannot find such disclosure in Hai ('842). Rather, Hai ('842) merely discloses the use of an "electric razor." See, e.g., page 2, line 48, page 6, lines 12-13, and Examples 7-11 of Hai ('842)." Rather Hai ('842) is silent as to the design of razor to be used. However, it is likely a clipper-type razor that is often used to shave animals that does not comprise "a sheet containing at least one opening."

As set forth in Section 2131 of the MPEP (citing *Verdegaal Bros. v. Union Oil Co.*) "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Hai ('842) fails to disclose, or suggest, the specific shear device disclosed in pending independent claim 1 which is a shear device comprising the element of "a sheet containing at least one opening." Hai et al., thus, also fails to disclose the method of using such a shear member such that "where said sheet is contacted with said membrane such that a portion of said membrane is forced through said opening and ablates said portion of said membrane exposed through said opening." In addition, Hai ('842) also fails to disclose, or suggest, the elements of "wherein said portion of said membrane is forced into said opening by a pressure force" as recited in dependent claim 3 and "wherein said shear member moves parallel to said shear sheet" as recited in dependent claims 20 and 21.

Hai ('842), thus, also fails to anticipate claim 1, and accordingly also fails to anticipate claims 2-4, 6-9, 11-13, and 20-21, which depend from claim 1. Accordingly, Applicants respectfully request that this rejection under 35 USC 102(b) be withdrawn.

REJECTION UNDER 35 USC 103

I

Claims 5 and 10 were rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of US Patent No. 5,441,490 (hereinafter "Svedman ('490)"). See pages 3-4 of the Office Action. According to the Office Action, "Svedman ('490) discloses a similar method of delivery" See page 3 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) fails to disclose, or suggest, the method of pending independent claim 1. Svedman ('490) is also silent with respect to the use of such shear device. Rather, Svedman ('490) discloses the use of a pin to puncture the membrane. See, e.g., page 6, lines 4-6 of Svedman ('490). Thus, as both Hai ('842) and Svedman ('490) both fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the methods recited in dependent claims 5 and 10. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

II

Claims 14 and 15 were rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of PCT Patent Application WO 89/01338 (hereinafter "McMichael"). See page 4 of the Office Action. According to the Office Action, "McMichael discloses a similar method in which a vaccine against Staphylococcus aureus is administered." See Page 4 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) fails to disclose, or suggest, the method of pending independent claim 1. McMichael is also silent with respect to the use of such shear device. Thus, as both Hai ('842) and McMichael both fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the methods recited in dependent claims 14 and 15. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

III

Claims 16 and 17 were rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of US Patent No. 6,219,574 (hereinafter "Cormier et al. ('574)"). See page 4 of the Office Action. According to the Office Action, "Cormier et al. ('574) discloses a similar method in which a glucose molecule is transported out through the membrane." See page 4 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) fails to disclose, or suggest, the method of pending independent claim 1. Cormier et al. ('574) is also silent with respect to the use of such shear device. Thus, as both Hai ('842) and Cormier et al. ('574) both fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the methods recited in dependent claims 16 and 17. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

IV

Claims 16 and 17 were rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of US Patent No. 6,678,554 (hereinafter "Sun et al. ('554)"). See pages 4-5 of the Office Action. According to the Office Action, "Sun et al. ('554) describes a similar method in which an impedance sensor is used to measure the impedance of the barrier membrane." See page 5 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) fails to disclose, or suggest, the method of pending independent claim 1. Sun et al. ('554) is also silent with respect to the use of such shear device. Thus, as both Hai ('842) and Sun et al. ('554) both fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the methods recited in dependent claims 16 and 17. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

V

Claim 23 was rejected under 35 USC 103 as being unpatentable over Hai ('842) and Sun et al. ('554) in view of US Patent No. 4,406,658 (hereinafter "Lattin et al. ('658)"). See pages 5-6 of the Office Action. According to the Office Action, "Lattin et al. ('658) describes a similar method in which a microprocessor received measurements from an impedance sensor." See page 6 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) and Sun et al. ('554) both fail to disclose, or suggest, the method of pending independent claim 1. Lattin et al. ('658) is also silent with respect to the use of such shear device. Thus, as both Hai ('842), Sun et al. ('554), and Lattin et al. ('658) fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the method recited in dependent claim 23. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: _____/William E. McGowan/____
William E. McGowan
Reg. No. 39,301

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2197